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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,739	05/26/2004	Itzhak Bentwich	050992.0302.CPUS00	3738
37808	7590	08/28/2007	EXAMINER	
ROSETTA-GENOMICS			SCHNIZER, RICHARD A	
c/o PSWS			ART UNIT	PAPER NUMBER
700 W. 47TH STREET			1635	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/709,739	Applicant(s) BENTWICH ET AL.	
	Examiner Richard Schnizer, Ph. D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2004 and 02 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment was received and entered on 1/2/07.

Claims 1-22 were canceled and claims 23-34 were added as requested.

Applicant's election without traverse of group 1 is acknowledged. Applicant's further election of SEQ ID NO: 4204050 with traverse is acknowledged. Traversal is on the grounds that 37 CFR 1.141 permits examination of a reasonable number of sequences, that 10 sequences constitutes a reasonable number (MPEP 803.04), and that the Examiner has not demonstrated that the claimed sequences are an exceptional case. This is unpersuasive. MPEP 803.04 indicates that *up to ten* sequences may be considered. Applicant's attention is also directed to the Notice published in the Official Gazette (1316 OG 122) which as of February 22, 2007 supersedes MPEP 803.04. The announcement states in part:

"The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications.

For National applications filed under 35 U.S.C. 111(a), polynucleotide inventions will be considered for restriction, rejoinder and examination practice in accordance with the standards set forth in MPEP Chapter 800 (except for MPEP 803.04 which is superseded by this Notice). Claims to polynucleotide molecules will be considered for independence, relatedness, distinction and burden as for claims to any other type of molecule.

The various sequences set forth in the claims as originally filed are independent and distinct for the reasons of record, i.e. different structures and functions, and the restriction requirement is deemed proper and is hereby made FINAL. Because newly

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claimed SEQ ID NOS: 117937 and 118171 are found within the 67 nucleotides of elected SEQ ID NO:4204050, they will be examined as well.

Claims 23-34 are pending and under consideration.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the citizenship of each inventor.

The full name of each inventor (family name and at least one given name together with any initial) has not been set forth.

The oath/declaration signed by the inventors does not list their names, or any citizenship or address information.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 23 is drawn to an isolated nucleic acid of 19 to 140 nucleotides. At page 11 of the response filed 1/2/07, Applicant indicates that support for this amendment can be found throughout the application and at paragraphs 49 and 50. A review of the application, and paragraphs 49 and 50, reproduced below, revealed no such support.

[0049] A "Hairpin Structure" is defined as an oligonucleotide having a nucleotide sequence that is 50-140 nts in length, the first half of which nucleotide sequence is at least partially complementary to the second part thereof, thereby causing the nucleic acid to fold onto itself, forming a secondary hairpin structure.

[0050] A "Hairpin-Shaped Precursor" is defined as a Hairpin Structure which is processed by a Dicer enzyme complex, yielding an oligonucleotide which is about 19 to about 24 nts in length.

These paragraphs support an oligonucleotide of 50-140 nucleotides, and a product of Dicer that is 19-24 nucleotides in length. The only context in which '19' is used as a lower limit of a range is that of Dicer products, and these products range only from 19 to 24 nucleotides. So, 24 nucleotides is the only upper limit that is contemplated in combination with the lower limit of 19. There is no support for the combination of the 140 nucleotide upper limit with the 19 nucleotide lower limit in the context of isolated nucleic acids generally.

Claim 23 also recites "at least 19 nucleotides of SEQ ID NO:4204050". Applicant relies for support for this limitation on Table_2_B, lines 4474648-4474741 and 4617066-

4617159. This does not suffice as support for the amendments, because the Table does not have line numbers, and the Examiner was unable to find the indicated passages after reasonable effort.

Claim 23 also recites "a sequence at least 52/67 identical to" a nucleic acid of 19 to 140 nucleotides comprising at least 19 nucleotides of SEQ ID NO: 4204050. Applicant relies for support for the fraction 52/67 on Table 4, lines 608189-608195, which shows that SEQ ID NO:4204050, which is 67 bases long, forms a hairpin in which 52 complementary nucleotides are paired. The Examiner notes that this information is also available in Fig. 14B. This in no way provides support for a nucleic acid that is at least 77.6% (52/67) identical to 19 nucleotides of SEQ ID NO: 4204050, or for the vast majority of the other embodiments embraced. In fact, it does not even provide support for the genus of nucleic acids that are 52/67 identical to SEQ ID NO: 4204050. It provides support only for SEQ ID NO: 4024050. Note also that Table 4 does not have the line numbers indicated by Applicant.

Claim 26 has similar unsupported limitations.

Claim 25 recites the "nucleic acid of claim 23, wherein the nucleic acid consists of 19-24 nucleotides." Applicant relies for support on paragraph 50 of the specification (reproduced above). This passage provides support only for Dicer products of 19-24 nucleotides. It follows that this passage provides support only for expected Dicer products of SEQ ID NO: 4204050 which allegedly forms a hairpin substrate for Dicer. One of skill in the art appreciates that not all 19-24 nucleotide segments of SEQ ID NO: 4204050 will be produced by Dicer action, so the specification as filed did not fairly

support the limitation "the nucleic acid of claim 23, wherein the nucleic acid consists of 19-24 nucleotides." In fact only a fraction of the possible 19-24 nucleotide fragments of SEQ ID NO: 4204050 would be produced by Dicer activity, and the specification as filed did not disclose the sequences of these fragments. Accordingly, claim 25 recites new matter.

Claim 28 has similar unsupported limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamore et al (US 20060293267).

Zamore taught SEQ ID NO:19 (AAGUGACGGUGAGAUCCAGGCU) which consists of at least 19 nucleotides of instant SEQ ID NO: 117937, and consists of 22 nucleotides of instant SEQ ID NO: 4024050. See alignments below, and Table 1 at page 6 of Zamore. Zamore also taught vectors comprising the sequence, see e.g. paragraphs 132 and 135. These vectors are considered to be probes containing inserts consisting of the nucleic acid of instant claim 23. Note that Zamore claims priority to provisional

application 60/671,356, filed 4/13/06, which supports the relevant teachings of US 20060293267 at e.g. page 15, (disclosure of SEQ ID NO: 19), and pages 32 and 33 (disclosing vectors).

Thus Zamore anticipates the claims.

ALIGNMENTS OF INSTANT SEQ ID NOS: 4024050 AND 117937 WITH ZAMORE SEQ ID NO: 19.

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Query Match          95.5%;  Score 21;  DB 23;  Length 22;
Best Local Similarity 100.0%;  Pred. No. 11;
Matches    21;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

4024050          43 AAGUGACGGUGAGAUCCAGGCU 64
                  |||
ZAMORE           1 AAGUGACGGUGAGAUCCAGGCU 22
                  |||
117937           1 AGUGACGGUGAGAUCCAGGCU 21
```

Conclusion

No claim is allowed.

SEQ ID NO: 118171 is free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, J. Douglas Schultz, can be reached at (571) 272-0763. The official central

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fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Richard Schnizer, Ph.D.
Primary Examiner
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